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30955 LATHROP &	7590 07/24/2007 GAGELC		EXAMINER	
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SUITE 300 BOULDER, CO 80301			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/617,565	NIE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Anthony Weier	1761				
The MAILING DATE of this communication ap	pears on the cover sheet with the o	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	PATE OF THIS COMMUNICATION  136(a). In no event, however, may a reply be tir  will apply and will expire SIX (6) MONTHS from  e. cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 15 M	<u>//ay 2007</u> .					
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	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.				
Disposition of Claims						
<ul> <li>4)</li></ul>	is/are withdrawn from considerati	on.				
Application Papers						
9)☐ The specification is objected to by the Examine 10)☐ The drawing(s) filed on is/are: a)☐ acc		Evaminar				
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correct	•	* *				
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documen 2. Certified copies of the priority documen 3. Copies of the certified copies of the priority documen application from the International Burea * See the attached detailed Office action for a list	ts have been received. ts have been received in Applicat prity documents have been receive tu (PCT Rule 17.2(a)).	ion No ed in this National Stage				
Attachment(s)  1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summary					
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate				

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06) Application/Control Number: 10/617,565

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-5, 7-16, 24, 25, 27-33, 41, 42, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/13521 (Wang et al).

Wang et al discloses a resin formation formed into a pet chew treat wherein said resin formulation may contain animal protein (e.g. egg white) and plant protein (e.g. wheat, corn) wherein same may be used alone or in combination and wherein said protein may be either native or hydrolyzed, said formulation being palletized (page 8). Example 7 discloses the use of approximately 50% soy protein isolate (e.g. the grain protein called for in the instant claims) and approximately 10% animal protein or protein derivative of same. Although it is not specified in this example that the animal-derived protein is hydrolyzed, it would have been obvious to one having ordinary skill in the art to have hydrolyzed same (with or without the grain protein) to contribute to or provide better processing flowability (see page 3). As for the particular molecular weight of said protein (instant claims 24 and 25), absent a showing of unexpected results, it would have been further obvious to have arrived at same as a matter of preference depending on the particular protein moiety available or the cost of same.

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Wang et al also discloses the presence of a plasticizer (e.g. glycerol) in an amount of as high as 30%, water as low as 10% (see claim 1), and vegetable powders (as the additional ingredient of claim 41) in an amount of, for example, 2% in Example 7.

The claims further call for the grain protein in the pellets to be substantially undenatured. Although Wang does provide in the examples a temperature strategy for extruding the pellets, there is no restriction on the temperature to be used other than providing a product having good flow when used in preparing the injected molded article. It should be further noted that with respect to the temperatures strategy employed, for example, in Example 1, would not result in a grain protein that is denatured, if at all, particularly since the exposure to such temperatures is not long enough to cause denaturation. As further evidence it should be noted that a corn gluten meal is denatured by treating same to a temperature of 100-120 C for 30-300 minutes<sup>1</sup>. It is expected that exposure of the grain protein mixed with the other components as well as the moisture content therein would further facilitate avoidance of and protection from notable denaturation using the temperature strategy specifically set forth in the Examples of Wang.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al and Axelrod et al (U.S. Patent No. 6159516).

The claims further call for the presence of the protein originating from chicken liver. Such are well known as taught, for example, by Axelrod et al that teaches a

<sup>&</sup>lt;sup>1</sup> See, for example, claim 1 of Carlson et al U.S. Patent No. 5759223

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molded chewable pet food which contains a liver protein material (col. 8, lines 55-62). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included liver protein in the product of Wang et al as a matter of preference depending on what protein is available, the cost of same, and the nutritional needs of the pet and to have further hydrolyzed same as discussed in the rejection above.

4. Claim 34, 35, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al and Pater et al.

The claims further call for the presence of a lubricator in amounts and type as called for in the instant claims. Pater et al discloses a molded chewable pet food containing lubricants such as fatty acid derivatives and in amounts as high as 5%. It would have been obvious to one having ordinary skill in the art at the time of the invention to have included same for the art recognized flow enhancing effect attributed to same.

The claims also call for the presence of a mold release agent. Pater et al further teaches incorporating same (calcium stearate; see claim 12). It would have been further obvious to have included same for such art recognized use. As for the amount of same employed, such would have been well within the purview of a skilled artisan, and it would have been further obvious to have arrived at same through routine experimental optimization.

5. Claims 34-36, 38-44 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al and Jane et al.

The claims further call for the presence and amount of a particular reducing agent. Jane et al teaches an edible molded article (which may be used for pets; col. 7, lines 49-60) prepared from a soybean material wherein a reducing agent such as sodium pyrosulfite (i.e. sodium metabisulfite) is incorporated to aid in the dispersibility of the protein component in preparing the material to be molded (e.g. col. 1, lines 23-37; claim 10). It would have been obvious to one having ordinary skill in the art at the time of the invention to have employed same in the Wang et al product for such reason.

The claims also call for the presence of modified starch of a particular type and amount. Jane et al further teaches the use of a chemical modified starch and a starch sourced from, for example, wheat or corn (e.g. col. 3, lines 54-67) wherein same is used in conjunction with soybean protein material. It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated such starch as a filler to provide "better flowability, better water resistance, and to decrease the cost of same" (col. 3, line 47-53). As for the amount of same to be used, Jane et al teaches the preparation employing 20-30% of same. It would have been further obvious to have employed such amount in Wang et al for such benefit.

The claims further call for a mold release agent and amount of same. Jane et al teaches such an agent (e.g. lubricant; col. 4, lines 31-36), and it would have been further obvious to have incorporated same for such reason. It would have been well within the purview of a skilled artisan to determine the particular amount of agent to be

used, and it would have been further obvious to have arrived at such amount as a result effective variable.

The claims call for the presence of a lubricant such as fatty acid. Jane et al. further teaches the use of same (col. 4, lines 31-36), and it would have been further obvious to have employed same for the reasons above: to facilitate the removal of the product from its molding device. It would have been well within the purview of a skilled artisan to determine the particular amount of agent to be used, and it would have been further obvious to have arrived at such amount as a result effective variable.

## Response to Arguments

6. Applicant's arguments filed 5/15/07 have been fully considered but they are not persuasive.

Applicant argues that Wang does not disclose specific amounts of hydrolyzed protein as well as the use of hydrolyzed protein derivatives as called for in the instant claims. The rejections, however, address the use of animal-derived protein or protein derivative of same and the use of hydrolyzed animal derived protein for providing better processing flowability (see page 3 in Wang). As for the particular type of derived protein employed (addressed in the rejection with respect to the particular molecular weight of the protein), absent a showing of unexpected results, same would have been obvious to one having ordinary skill in the art at the time of the invention as a matter of preference depending on, for example, cost or availability of same.

Applicant argues that there is no motivation to hydrolyze the liver protein of Axelrod in the formation of Wang. However, absent a showing of unexpected results, it Art Unit: 1761

would have been obvious to have employed a hydrolyzed protein form for the reasons set forth in Wang (e.g. better processing flowability). Applicant further suggests that Axelrod teaches away from employing a hydrolyzed form since hydrolyzing is known to cause bitterness and off-flavors and the liver component in Axelrod is used as an attractant. It should be noted, however, that Axelrod employs the liver component to also improve the quality or strength characteristics of the subsequent molded products (i.e. col. 8, lines 57 and 58). Moreover, the liver component is not the only flavoring component used in the Axelrod composition (e.g. turkey), and no evidence has been provided that the flavoring would lose its attribute of attraction by hydrolyzing same, particularly since liver protein is not the only flavoring material employed (e.g. chicken, ham, etc. components may be used in combination with the liver) and because providing bitterness or off-flavors may be an attractant in an of itself.

Applicant argues that Pater et al employs calcium stearate as a lubricant or flow property enhancer and not a mold release agent. It should be noted that the use of a lubricant would naturally enhance or aid in mold release. Moreover, calcium stearate is art recognized as a mold-release agent<sup>2</sup>.

Applicant argues that Jane et al teaches high temperature treatment which would lead to protein denaturation (contrary to the requirement in the instant claims that the grain protein be substantially undenatured). However, it should be noted that Jane et al was applied in combination with Wang, the primary reference which teaches most of the claim limitations including a product with a grain protein that is substantially

<sup>&</sup>lt;sup>2</sup> See Hawley's Condensed Dictionary, 14<sup>th</sup> Edition.

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undenatured (as addressed in the rejection above). In other words, Jane et al was not applied for its extrusion treatment and likely denatured final product, but rather, as an example of the art recognized use of reducing agents and particular chemically modified starches in the field of edible molding material.

All other arguments have been addressed in view of the rejections as set forth above.

### Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000

> Anthony Weier **Primary Examiner**

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**Anthony Weier** July 16, 2007